

Transcutaneous tibial nerve stimulation for the treatment of faecal incontinence: results of a prospective study

Ieva Stundienė,

Paulius Žeromskas,

Jonas Valantinas

*Clinic of Gastroenterology,
Nephrourology and Surgery,
Faculty of Medicine,
Vilnius University,
Lithuania*

Background. Transcutaneous tibial nerve stimulation is a simple, non-invasive treatment, which can be used to treat faecal incontinence. Optimal treatment regimen is not known and various stimulation regimens are used in different centers. The aim of this prospective study was to evaluate the efficacy of twice weekly transcutaneous tibial nerve stimulation for faecal incontinence patients, who have failed to respond to maximal conservative treatment.

Material and methods. Twenty patients with faecal incontinence resistant to maximal conservative therapy were treated with transcutaneous posterior tibial nerve stimulation twice a week for six weeks. The number of the bowel movements per two weeks and the Cleveland Clinic Florida Faecal Incontinence Score were assessed before and after the treatment. The quality of life was estimated using the Faecal Incontinence Quality of Life questionnaire and the Gastrointestinal Quality of Life Index.

Results. Effect was seen in 55% of patients. Two-week faecal incontinence episodes decreased from median 4 (2–84) to 2 (0–56) ($p = 0.002$). The mean Cleveland Clinic Florida Faecal Incontinence score improved from 10.9 ± 4.34 to 7.8 ± 3.96 ($p = 0.002$). The quality of life improved significantly after the treatment. The therapy was well tolerated and no participant experienced any adverse event.

Conclusions. Transcutaneous tibial nerve stimulation twice a week for 6 weeks may be efficacious in patients with faecal incontinence, who have failed to respond to maximal conservative treatments.

Key words: transcutaneous electric nerve stimulation, faecal incontinence, tibial nerve

INTRODUCTION

Faecal incontinence (FI) is a common problem, especially in older population, leading to physical and psychological disability and social isolation (1, 2). The estimated prevalence of FI varies from 0.5% to 28%, with a female / male ratio of six to eight times (3, 4). However, the true prevalence is unknown (5) because of embarrassment and isolation.

Considering the problem of aging population, FI is likely to be even a greater burden in the future (6). Treatment of FI is challenging, because conservative treatment measures have lasting success in approximately 50% of patients (7). Surgical treatment options carry significant risk of complications (8, 9) and have well-established high long-term failure rates (6).

Currently, neuromodulation is one of the fastest growing areas in medicine. It is intermediary therapy between conservative and surgical treatment methods. At present modulation of the sacral plexus with sacral nerve stimulation (SNS) is widely used in clinical practice and has become the standard treatment (1) of urinary and faecal incontinence (10–12). SNS is a moderately invasive therapy with significant risk of complications and a high financial cost (9, 13).

The peripheral neuromodulation of the sacral nerve plexus can be done with less invasive and technically simpler neuromodulatory therapies. Tibial nerve stimulation with needle electrodes (percutaneous tibial nerve stimulation [PTNS]) or adhesive electrodes (transcutaneous tibial nerve stimulation [TTNS]) is used to treat urinary incontinence and overactive bladder syndrome as well as faecal incontinence (14–16). Tibial nerve stimulation is a simple, well-tolerated and a low-cost technique.

Many different regimens of PTNS from once daily to once weekly have been reported. In most TTNS studies the stimulation was performed once daily.

The aim of this prospective study was to evaluate the efficacy of twice weekly TTNS for FI patients, who have failed to respond to maximal conservative treatment.

MATERIALS AND METHODS

Study population

From November 2011 to June 2013 twenty patients with faecal incontinence, who were referred to a

specialized centre and satisfied the inclusion and exclusion criteria, were prospectively enrolled in the consecutive cohort study. The inclusion criteria were age over 18 years, faecal incontinence with solid or liquid stool causing disruption of lifestyle, symptoms present for a minimum of one year, psychological stability, failed conservative therapy and adequate motor and / or sensory response during treatment. The exclusion criteria were major internal and / or external sphincter defect (>120 degrees of circumference), any organic pathology causing FI, inflammatory bowel disease, congenital anorectal malformations, neurogenic or congenital disorders resulting in faecal incontinence (Multiple Sclerosis and Spina Bifida), pregnancy or intention to become pregnant, an implanted pacemaker or a defibrillator, diabetes mellitus, severe distal venous insufficiency and severe cutaneous local lesion.

Assessment

Pretreatment evaluation included detailed history, physical examination, endo-anal ultrasound, defecography, anorectal manometry and rectal sensation testing.

FI was assessed by 2-week bowel habit diaries at the baseline before the first treatment session and during follow-up at 6 weeks. The primary outcome measure was the reduction in incontinence episodes per 2 weeks. We also assessed the Cleveland Clinic Florida Faecal Incontinence Score (CCF-FI score) at the baseline and after 6 weeks. The CCF-FI score rates the severity of FI on a scale of 0–20, with a higher score indicating more severe complaints (17).

The effect of treatment on the quality of life was assessed using the FI quality of life questionnaire (FIQL) and the Gastrointestinal Quality of Life Index (GIQLI) at the baseline and after 6 weeks of treatment. The FIQL questionnaire is disease-specific for FI and measures the quality of life in four domains (lifestyle, coping / behaviour, depression and embarrassment) on a scale of 1–4 (18). The GIQLI questionnaire consists of 36 questions that assess the impact of disease on the physical, social and mental status (19).

Defecography was performed by retrograde infusion of radiopaque contrast and assessing rectal configuration and perineal descent while the patient was resting, contracting the anal sphincter, and straining to defecate (20). Anorectal physiol-

ogy included rectal sensory testing and rectoanal inhibitory reflex. Rectal sensory testing was performed by distending the rectum with an air-filled balloon. Rectal volumes to distension for the first sensation of urge, sensation of desire to defecate and the maximum tolerated volume were recorded in millilitres (21).

Every patient served as his or her own control. The study was approved by the Ethics Committee of Vilnius University and every patient signed a written informed consent.

Procedure

TTNS was done with a stimulating Neuro Track TENS unit (Verity Medical, UK). Stimulation was done on the tibial nerve route using a self-adhesive surface stimulation electrode (16, 22). A negative electrode was placed on the ankle skin behind the internal malleolus with the positive electrode being placed 10 cm above the negative one. The adequate position of the electrode was determined by slowly increasing the electric current until sensory and / or motor responses were evident. Typical responses included foot sole sensation and / or great toe flexion (15). The appropriate electric current intensity level was determined based on the intensity immediately under the threshold motor contraction and varied from 18 to 38 mA. The fixed pulse width of 200 μ s and a frequency of 20 Hz were applied in a continuous mode for 30 min. TTNS was done in the Outpatient Department twice weekly for 6 weeks (12 procedures) (15).

Statistical analysis and sample size

With reference to previous studies (14) and the initial data of our study, we estimated that 20 patients would be necessary to detect an improvement of FI in 50% with a power of 90% at a significance level of 0.05.

Continuous variables were checked for normal distribution by the Shapiro-Wilk test. Normally distributed data were expressed as mean and standard deviations, and nonparametric data were expressed as median and range. Paired tests were used to compare data at the baseline and after the treatment: paired t-test for parametric, Wilcoxon signed-ranks test for nonparametric variables. The Mann-Whitney U test was used to compare unpaired data at the baseline and after the treatment. A p-value <0.05 was considered statistically significant.

RESULTS

Between 2011 and 2013 twenty patients underwent TTNS for faecal incontinence. All patients completed 12 sessions of TTNS in 6 weeks, filled in bowel diaries, FIQL and GIQLI questionnaires. Patients' characteristics are shown in the Table.

Table. Patients' characteristics

Baseline demographics	
Age (years)	68.5 (30–84)
Gender (male / female)	4/16
Years of incontinence (years)	4 (1–18)
Anal manometry	
Resting pressure, mmHg	36.61 \pm 19.74
Squeeze pressure, mmHg	75.31 \pm 23.87
Endoanal ultrasound	
Intact sphincter complex	15
External sphincter defect	2 (partial)
Internal sphincter defect	3

Clinical outcome

Of the 20 patients, 11 (55%) had a 50% or greater reduction in incontinence episodes at 6 weeks of follow-up. The overall median two-week faecal incontinence episodes decreased from 4 (range 2–84) pre-treatment to median 2 (range 0–56) post-treatment ($p = 0.002$). In the effect subgroup a median of 4 (range 2–70) faecal incontinence episodes per two weeks at the baseline decreased to a median of 1 (0–10) after the treatment ($p = 0.005$).

The overall mean CCF-FI score improved significantly with treatment from 10.9 ± 4.34 to 7.8 ± 3.96 ($p = 0.002$). In the subgroup analysis, 11 patients with successful treatment had a mean baseline CCF-FI score of 11.1 ± 4.48 , which improved to a mean score of 5.7 ± 2.58 after TTNS ($p = 0.005$) (Fig. 1).

The GIQLI improved significantly in all domains after 6 weeks (Fig. 2).

The disease-specific assessment with the FIQL questionnaire showed improvements in all four domains. The overall mean score of the lifestyle domain increased from 2.56 ± 0.8 pre-treatment to 2.92 ± 0.83 post-treatment ($p = 0.001$), coping domain from 2.05 ± 0.7 to 2.49 ± 0.75 ($p = 0.003$), depression domain from 2.76 ± 0.56 to 3.08 ± 0.65

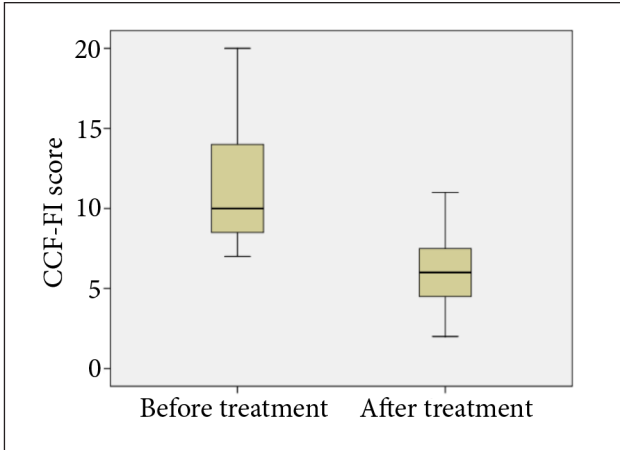


Fig. 1. CCF-FI score changes before and after the treatment in the effect group

($p = 0.007$) and embarrassment domain from 1.83 ± 0.62 to 2.2 ± 0.66 ($p = 0.003$). The changes of the FIQL score in the effect subgroup are shown in the picture (Fig. 3).

Comparison between the success and failure groups did not help to define initial conditions predictive of a symptomatic improvement. Both groups had similar age, symptom duration, CCF-FI score, number of faecal incontinence episodes, FIQL and GIQLI scores at referral.

The therapy was well tolerated and no participant experienced any adverse event.

DISCUSSION

The results of this study showed that TTNS twice a week for 6 weeks may be efficacious in patients with faecal incontinence, who failed to respond to maximal conservative treatment.

TTNS effect, defined as 50% or greater reduction in incontinence episodes per two weeks, was achieved in more than a half of patients (55%). Significant decrease was seen in faecal incontinence episodes and in the CCF-FI score. The quality of life increased after the treatment. There was a statistically significant improvement in all FIQLI and GIQLI subscales.

The reported efficacy of PTNS and TTNS in faecal incontinence studies varies from 54% to 84.3% (15, 16, 22–25). Nevertheless, these are small, uncontrolled trials with different outcome measures and heterogeneous patient populations. The comparison with results of other TTNS and PTNS studies is complicated, because of different outcome measures used. In several studies a faecal incontinence score or even a visual analogue score, not a change in incontinence episodes, was used as a primary endpoint. Furthermore, various stimulation parameters and regimens have been used. The primary outcome measure of our study was the reduction of incontinence episodes per 2 weeks. The decrease of FI episodes per unit of time was the most

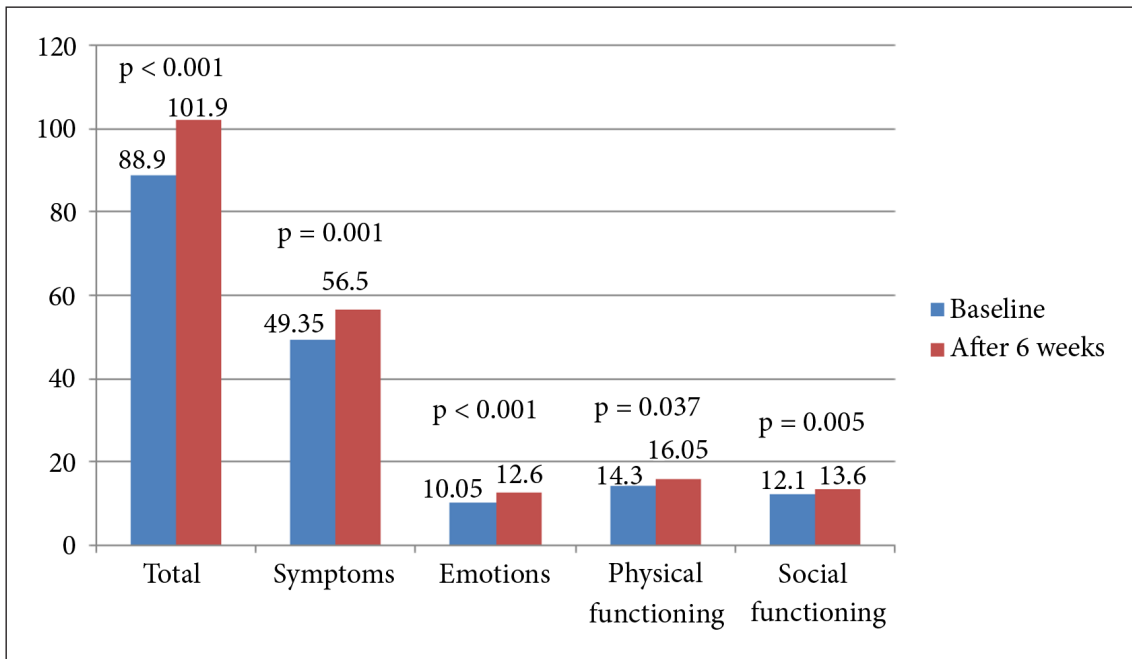


Fig. 2. GIQLI changes before and after the treatment

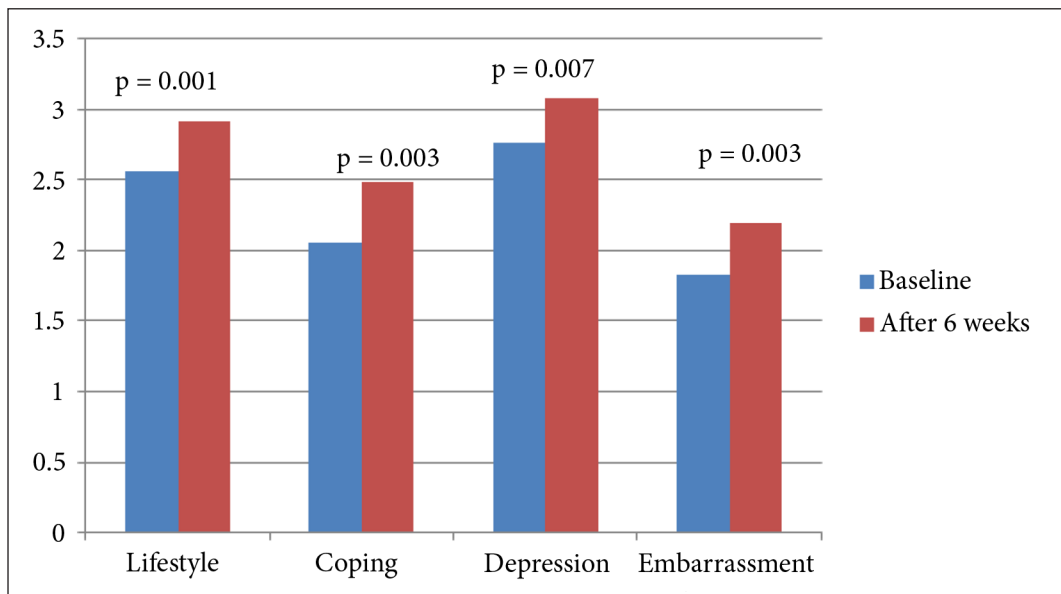


Fig. 3. FIQL score changes before and after the treatment

frequently used measure in SNS studies (26–29) and is considered to be least affected by subjective reporting. However, being a count, this variable has a Poisson distribution and has greater variability than expected. This raises major difficulties in defining a clinically significant mean reduction in FI episodes within a population of patients with widely dispersed initial FI frequencies. To counter this problem, contemporary studies (26–29) have adopted a primary outcome for ‘success’, using a categorical measure of percentage reduction (the proportion of patients who have a 50% or greater reduction in FI episodes per week) (1).

A disease-specific QoL questionnaire is also essential to measure therapeutic options for FI patients (30). Usually they are anxious and socially disabled because of the fear of embarrassment (1). For this purpose we used FIQLI and GIQLI questionnaires.

The treatment with TTNS and PTNS is not standardized and the optimal regimen is not known. Various different frequencies have been described in the literature varying from twice daily for 3 months to every other day for 4 weeks (12, 31). In most TTNS studies the stimulation was performed every day by patients themselves. Moreover, in some studies the treatment course lasted longer, about 3 months and more (22, 24). In order to avoid bad patient compliance and to perform procedure in a correct standardized manner, TTNS in our study was done in the outpatient

department twice a week for 6 weeks, like in the most PTNS studies (14). Presumably a better effect might be observed after 3 months of daily stimulation.

The TTNS was well tolerated; the compliance of the patients was very good, no adverse events occurred. The same results were seen in other TTNS studies (16, 22, 24), whereas adverse effects such as gastrodynia, paraesthesia or numbness and bleeding from the needle site have been reported in several PTNS studies (9, 15, 28).

The limitation of our study was quite a small group of participants. Nevertheless, most published TTNS and PTNS studies with FI patients are small, uncontrolled and with heterogeneous patient populations (9, 14). Only 15–45% of those suffering from FI consult medical services, owing to embarrassment and lack of knowledge about potential treatments (32, 33).

Another drawback was the absence of the control group with sham TTNS to eliminate the placebo effect. Correct electrode placement and current amplitude is confirmed by sensory and / or motor response of the foot, thus blinding in such treatment method is difficult. PTNS is thought to neuromodulate the sacral nerve plexus through the tibial nerve. Effects beyond placebo suggest findings that PTNS modulates ascending spinal pathways (34) and long-term latency somatosensory evoked potentials (35, 36), leading to changes in colonic motility, anal sphincter activity and modulation of

higher perception of afferent information (36, 37). However, no anorectal physiological changes are consistently observed from PTNS and SNS (38). In studies with urinary incontinent patients PTNS has been shown to be significantly more effective than sham stimulation (39).

Larger studies with better design and control groups are needed to rule out the placebo response. It remains unclear how long and how often the stimulation should be done, and which patients are most likely to benefit from the therapy.

CONCLUSIONS

TTNS is an effective treatment method for faecal incontinence. We have shown that good results can be obtained with less frequent treatment sessions. It is a safe, noninvasive, technically simple procedure, which can be easily performed in an outpatient setting or at home.

ACKNOWLEDGEMENTS

The study was supported by the project “Development of Training of Highly Qualified Professionals Satisfying the Requirements of the State and Society in the Field of Biomedicine – BIOMEDOKT”, Project No. VP1-3.1-SMM-01-V-03-002.

Received 1 July 2014

Accepted 7 July 2014

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Ieva Stundienė, Paulius Žeromskas, Jonas Valantinas

**TRANSKUTANINĖ BLAUZDINIO NERVO
STIMULIACIJA IŠMATŲ NELAIKANTIEMS
PACIENTAMS: PROSPEKTYVINIO TYRIMO
REZULTATAI**

Santrauka

Įvadas. Transkutandinė blauzdinio nervo stimuliacija yra lengvai atliekamas neinvazinis gydymo metodas, kuriuo gali būti gydomi išmatų nelaikantys pacientai. Optimalus šio gydymo režimas nėra nustatytas, todėl skirtinguose centruose stimuliacija atliekama įvairiais režimais. Šio prospektyvinio tyrimo tikslas – įvertinti du kartus per savaitę atliekamos transkutandinės blauzdinio nervo stimuliacijos efektyvumą išmatų nelaikantiems pacientams, kuriems neefektyvus maksimalus konservatyvus gydymas.

Medžiaga ir metodai. Dvidešimt išmatų nelaikančių pacientų du kartus per savaitę šešias savaites buvo gydomi taikant transkutandinę blauzdinio nervo stimuliaciją. Vertinti išmatų nelaikymo epizodų skaičiaus per dvi savaites, Klyvlendo klinikos išmatų nelaikymo skalės ir gyvenimo kokybės klausimynų balų pokyčiai prieš ir po gydymo.

Rezultatai. Efektas stebėtas 55 % pacientų. Išmatų nelaikymo epizodų skaičiaus mediana per dvi savaites po gydymo sumažėjo nuo 4 (2–84) iki 2 (0–56) ($p = 0,002$). Vidutinis Klyvlendo klinikos išmatų nelaikymo skalės balas sumažėjo nuo $10,9 \pm 4,34$ iki $7,8 \pm 3,96$ ($p = 0,002$). Po šešių savaičių ženkliai pagerėjo pacientų gyvenimo kokybė. Nepastebėta jokių šalutinių poveikių, pacientai gerai toleravo gydymą.

Išvados. Transkutandinė blauzdinio nervo stimuliacija, atliekama du kartus per savaitę šešias savaites, gali būti efektyvi priemonė išmatų nelaikantiems pacientams.

Raktažodžiai: transkutandinė blauzdinio nervo stimuliacija, išmatų nelaikymas, blauzdinis nervas